

DAIDS

VIROLOGY MANUAL

FOR HIV LABORATORIES

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Compiled by

THE DIVISION OF AIDS

NATIONAL INSTITUTE OF ALLERGY & INFECTIOUS DISEASES

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and

COLLABORATING INVESTIGATORS

INTRODUCTION

The purpose of a laboratory manual is to provide a standardized methodology for assay performance. Standardized methodologies minimize variability and allow for the comparison of results from laboratory to laboratory. Method standardization is a critical component of the clinical laboratory where the values obtained are used to monitor and treat patients. Unlike the research setting where the results of an experiment may be unknown, the results obtained in the clinical setting are “expected” (normal values). The clinician and clinical researcher must be assured that deviations from expected results reflect true changes due to therapy and/or disease progression of the patient and not variation in the methodology.

The first versions of this manual were circulated among the virology laboratories of the AIDS Clinical Trials Group (ACTG) as individual consensus laboratory protocols for use in ACTG clinical trials. In January 1993, these documents were compiled into a laboratory manual, which was revised and reprinted in September 1994. The distribution of the manual and its use by groups outside of the ACTG laboratories has increased significantly over the past several years. In an effort to make the manual applicable to all researchers working in the field, as well as allow for its use in the clinical laboratory, the manual was revised extensively in keeping with the guidelines recommended by the Clinical Laboratory Improvement Act.

The development of consensus assays protocol included in the manual has required a group effort involving many individuals working in the area of HIV virology. However, the compilation of this version of the manual has been accomplished by the DAIDS Virology Technologist Subcommittee. It is a manual written by the technologist for technologist. As with any effort of this magnitude, there are a few individuals who deserve special recognition: past and present chairpersons of the Virology Technologist Subcommittee - Ms. Suzy Woznick (formally University of North Carolina, Chapel Hill), Ms. Carolyn Beatty (University of Minnesota) and Ms. Joan Dragavon (University of Washington, Seattle), along with Mr. Brian Staes of the Virology Quality Assurance Contract at Rush-Presbyterian-St. Lukes Medical Center have spent many hours writing, reviewing and rewriting. Finally, many thanks to Ms. Daniella Livnat of the NIH Division of AIDS Program Office, without whose tireless commitment, encouragement and organizational skills the entire project would have never succeeded.

The manual is recognized as an official NIH publication and should be cited as follows: **Division of AIDS, National Institute of Allergy and Infectious Diseases**. 1997. DAIDS Virology Manual for HIV Laboratories. Publication NIH-97-3828. U.S. Department of Health and Human services, Washington, D.C. It is anticipated that the manual will be available electronically through the World Wide Web during 1997 and that updates and revisions will be made as necessary.

Patricia S. Reichelderfer, Ph.D

Program Virologist